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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,436	03/27/2001	Remi Delansorne	01056	5099
23338	7590	10/19/2005	EXAMINER	
DENNISON, SCHULTZ, DOUGHERTY & MACDONALD 1727 KING STREET SUITE 105 ALEXANDRIA, VA 22314			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 10/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/787,436	DELANSORNE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 28 July 2005.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 23-78 is/are pending in the application.
- 4a) Of the above claim(s) 29-31, 42-44 and 53-57 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 23-28, 32-41, 45-52 and 58-78 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

1. This office action is in response to Amendment filed on July 28, 2005. Claims 1-22 have been cancelled. Claims 29-31, 42-44, and 53-57 have been previously withdrawn. Claims 23-28, 32-41, 45-52, and 58-78 are currently pending and are under examination.

### **Maintenance of Rejections**

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 23-28, 32-34, and 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirai et al. (U.S. 4,659,696). Hirai et al. teaches an LH-RH analog which is a polypeptide having the formula pGlu-His-Trp-Ser-Tyr-D-Ala-Leu-Arg-Pro-NHC<sub>2</sub>H<sub>5</sub> (or leuprorelin) and 5 g of alpha-cyclodextrin. This analog fits the formula of A, I, II, III, and IV defined in claims 23, 24, 25, 26, and 27. Tri-O-methylcyclodextrin is also taught (column 4, line 33). “Absorption enhancer” in claim 34 is being interpreted as any excipient or pharmaceutical carrier that would increase the stability of the peptide. Thus, the excipient or pharmaceutical carriers used by Hirai et al. would meet this limitation.

Claim 23 recites limitations that refer to the intended use of the pharmaceutical formulation. Where it is possible that structural differences exist between the formulation of Hirai et al. and that of the present invention, there is nothing recited in the claims that distinguishes the present invention from the prior art.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 23-28, 32-41, 45-52, 58-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (U.S. 4,659,696) in view of Mehlem (U.S. 2003/0162721 A1).

The 103(a) rejection is disclosed in the office action mailed December 16, 2004.

**Response to Applicant's Remarks**

Applicants state Hirai et al. does not anticipate the composition claims in the present application, because Hirai et al. does not disclose a pharmaceutical composition for the gastrointestinal delivery by oral administration of an LH-RH peptide analogue. Applicants state the preamble distinguishes the composition claims over the composition of Hirai et al.

Applicants traverse the 35 U.S.C. 103(a) rejection. Applicants state there is no mention or suggestion in Mehlem that  $\alpha$ -cyclodextrin enhances the biological activity of LH-RH peptide analogues when a composition comprising  $\alpha$ -cyclodextrin and an LH-RH peptide analogue is administered orally. Applicants state the Mehlem reference does not fill the gaps left by Hirai et al., and therefore do not teach or suggest the invention defined by the present claims.

Applicant's arguments filed June 16, 2005 have been fully considered but they are not persuasive. The current composition claims are drawn to a LH-RH peptide analogue in combination with  $\alpha$ -cyclodextrin. Hirai et al. does disclose a LH-RH peptide analogue with  $\alpha$ -cyclodextrin. Applicant is referred to MPEP 2111.02, "PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is

not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim");

**MPEP 2114, "APPARATUS CLAIMS MUST BE STRUCTURALLY  
DISTINGUISHABLE FROM THE PRIOR ART**

>While features of an apparatus may be recited either structurally or functionally, claims<directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); and also MPEP 2141.02 citing "*In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) (From the standpoint of patent law, a compound and all its properties are inseparable.)".

Mehlem does employ alpha-cyclodextrin for the oral administration of peptides (see paragraph [0022]), which is the problem that the present invention seeks to resolve. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

***Conclusion***

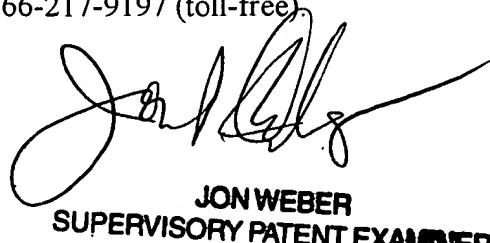
7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JON WEBER  
SUPERVISORY PATENT EXAMINER

October 12, 2005

